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EDITORIAL COMMENT

New Ways of Thinking About Senescent Bioprosthetic Heart Valve Therapy*

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In patients requiring heart valve replacement, biologic valve substitutes have been implanted with increasing frequency over the past decade. According to the Society of Thoracic Surgeons (STS) database, bioprosthetic valve implants in the aortic position have increased from 43.6% in 1997 to 78.4% in 2006 (1). A similar trend has been seen for mitral valve replacement (2). The trend has largely been driven by an effort to free patients from reliance on valve-related anticoagulation despite recent evidence warning of a possible negative prognostic impact in individuals younger than 60 years of age (3). Further, notwithstanding improvements in hemodynamics and durability of third-generation devices, bioprosthetic valves are associated with an increased risk of structural valve deterioration, particularly in patients younger than 65 years of age (4–7).

When bioprosthetic valves fail, reintervention has historically required repeat sternotomy; however, a significant proportion of these patients are at high risk of surgical reintervention. Transcatheter valve-in-valve (VIV) implantation has emerged as a less invasive alternative to surgical valve replacement, offered within the confines of clinical trials in select high-risk patients. Transcatheter VIV replacement permits treatment of stenotic or regurgitant biological surgical valves by anchoring an expandable device within the dysfunctional valve. Initial global experience can be summarized as follows: 1) patients were typically elderly with high surgical risk; 2) early series had very good periprocedural and clinical outcomes with low in-hospital mortality; 3) cases of elevated post-procedural gradients and compromised valve performance were reported despite symptomatic improvement; 4) cases of device dislodgment or embolization have been identified, especially after transcatheter mitral VIV implantation; and 5) life-threatening potential complications such as device malposition and coronary ostial coronary obstruction may require immediate surgical rescue (8–12). Despite the availability of these paradigm-changing early experiences with transcatheter VIV implantation suggesting safety and early efficacy for high-risk patients with failing bioprosthetic valves, longer term follow-up data to support wider adoption were previously unavailable.

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In the longest available follow-up to date, Ye et al. (13) present in this issue of *JACC: Cardiovascular Interventions* their 8-year single-center experience in 73 elderly high-risk surgical patients with symptomatic severe aortic and mitral bioprosthetic valve dysfunction undergoing transcatheter VIV implantation. The median STS risk score was 9.6. Most patients received balloon expandable SAPIEN or SAPIEN XT valves (Edwards Lifesciences, Inc., Irvine, California) via a transfemoral approach. Mitral VIV implantation was only performed using transapical access. The median follow-up was 2.52 years, and the longest was 8 years. Successful implantation occurred in 98.6% of patients with embolization of a SAPIEN valve into the left ventricle seen in 1 patient during transapical aortic VIV implantation requiring immediate conversion to open surgery. Overall 30-day mortality was 1.4%, with 88.9% and 40.5% of patients surviving at 1 and 5 years, respectively. These findings compare favorably with the 5-year follow-up data from the PARTNER cohort A study (14). An important independent predictor of

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diminished survival using multivariate analysis was small aortic surgical valve size (19 and 21 mm) versus those larger than 23 mm (hazard ratio: 6.186 [95% CI: 1.001 to 22.82]; p = 0.013). In terms of transcatheter valve performance, there was a significant reduction in surgical prosthetic valvular pressure gradients for both aortic and mitral valves and an increase in valve area after VIV therapy at 12-month follow-up. This translated into significant clinical improvement in heart failure symptoms that was durable for the majority of patients and for 1 patient up to 8 years.

These clinical findings identify for the first time the stability and laudable midterm performance associated with transcatheter VIV therapy. There are several key points to consider from this registry. First, the importance of multidisciplinary heart team assessment is paramount when deciding between open surgical valve revision and transcatheter VIV implantation. Both methods of treating senescent surgical bioprostheses are valid in the modern era, and therapeutic choices should be tailored according to patient risk factors, anatomy, and preference. Second, despite the very good midterm outcomes with VIV implantation, the report reflects the single-center experience of proficient transcatheter aortic valve implantation operators. Third, the transfemoral approach may have been associated with a reduced length of hospitalization. The operators used the transapical access for transcatheter mitral VIV implantation because they thought it provided direct and coaxial access; however, transvenous transcatheter mitral VIV implantation has also recently been shown to be feasible and safe (15). Fourth, despite symptomatic improvement, transcatheter valve hemodynamic performance was concerning in patients with aortic surgical valves 19 and 21 mm in size, which, according to the authors, could have diminished late survival. Comparatively, in a larger cohort of patients from interim PARTNER II NR3 VIV Registry data, there was no difference in 1-year outcomes with respect to surgical heart valve size (21 mm vs. >23 mm) or transcatheter valve size (23 mm vs. 26 mm). Fifth, preoperative evaluation using computed tomography (CT) angiography is essential regardless of the surgical valve used or knowledge of the manufacturer-reported valve dimensions. Anatomic and technical considerations identified during CT preoperative planning may minimize the risk of coronary occlusion, particularly in patients with stentless or internally stented bioprosthetic valves (16). Sixth, thrombus identified on some transcatheter mitral valves suggests that further study is needed regarding anticoagulation strategy after transcatheter mitral VIV implantation. Finally, although balloon valvuloplasty was used selectively in this registry in transfemoral cases with severe bioprosthetic stenosis without significant complications, it may not be uniformly required, which is important given potential susceptibilities of severe regurgitation, debris embolization, and stroke (17).

Transcatheter VIV implantation offers clinicians an important new treatment for high-risk patients with senescent bioprosthetic valves. Definitions of appropriate patient selection criteria and best practices during technical implantation are rapidly evolving as experience with this therapy grows. The present series advances our understanding of the midterm durability and clinical outcomes that can be expected several years after treatment. The potential for compromise of hemodynamic and survival outcomes must be acknowledged when VIV therapy is considered in patients with small (19 and 21 mm) surgical valves. Whether newer devices such as the SAPIEN 3 (18) or self-expanding, supra-annular transcatheter valves such as the CoreValve (Medtronic, Minneapolis, Minnesota) may better serve this population is unclear and requires further study. A multidisciplinary team of surgeons, interventionalists, and imaging experts should carefully select candidates for transcatheter VIV implantation. Moreover, because surgical rescue may be required in the event of coronary occlusion, valve embolization, or other complications, true collaboration during technical performance of the procedure is critical to keep all parties fully invested in ensuring the best outcome for the patient. The availability of transcatheter VIV implantation has changed the paradigm of senescent biologic heart valve therapy and should be performed at centers with mature transcatheter heart teams to replicate the superb midterm results obtained in the present series.

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